

### REMARKS

Claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 are pending. Claims 2, 3, 5, 7-9, 11-17, 19-20, 25-28, 33, 35-53 were previously canceled. Claims 1, 4, and 34 are amended herein to more clearly set forth aspects of the invention. New claim 54 is submitted herewith. Accordingly, amended claims 1, 4, and 34, and dependent claims therefrom, and new claim 54 are under consideration.

Any amendment is not to be construed as abandonment of any subject matter of the originally filed application. Accordingly, it is to be understood that Applicants reserve the right to reintroduce subject matter deleted from the application by the foregoing amendments and to file one or more divisional, continuation, and/or continuation in part applications directed to such subject matter.

Claims 1, 4, and 34 are amended herein. Support for the amendments to the claims is found throughout the specification and in the original claims. Specifically, support for amendment to claim 1 is found in original claim 1 and in the specification, for example, at page 7, lines 9-12 and at page 16, lines 22-27; and in Figure 4 and SEQ ID NO: 4 of the Sequence Listing. Support for amendment to claim 4 is found in original claim 4. Support for amendment to claim 34 is found in original claim 34 and in the specification, for example, at page 1, lines 24-27 and at page 13, lines 15-26. No issue of new matter is introduced by these amendments.

New claim 54 is presented herein. Support for new claim 54 is found throughout the specification and in the original claims. Specifically, support for new claim 54 is found in original claim 1 and in the specification, for example, at page 6, lines 1-6; and in Figure 4 and SEQ ID NO: 4 of the Sequence Listing. No issue of new matter is introduced by these amendments.

### Objections

Claim 1 is objected to for recitation of "SEQ.ID.NO:1". Applicants assume that the Examiner meant to refer to "SEQ. ID. NO: 4", which is recited in claim 1, rather than "SEQ.ID.NO:1", which is not presented in claim 1. In view of the amendment to claim 1, Applicants believe that the objection to the claim may be withdrawn.

**Rejections under 35 USC § 112**

Claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 are rejected under 35 USC § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner does, however, acknowledge that the specification is enabling for an isolated histamine binding peptide capable of binding to histamine or serotonin with a disassociation constant of less than  $10^{-7}$ M which comprises the amino acid sequence of SEQ ID NO: 4 and a method for treating allergic asthma comprising administering the protein of SEQ ID NO: 4. In view of the amendments to the claims, the rejection, as it applied to claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34, is respectfully traversed.

Claim 1 is amended to be directed to an isolated histamine or serotonin binding protein capable of binding to histamine or serotonin with a dissociation constant of less than  $10^{-7}$ M, wherein said isolated histamine or serotonin binding protein i) comprises the amino acid sequence of SEQ ID NO: 4 or an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4; ii) and which has a binding site comprising amino acid residues isoleucine at position I, tryptophan at position II, aspartate at position III and glutamate at position IV wherein residues I to IV are positioned at residues 139, 71, 67 and 112 in SEQ ID NO: 4 or are positioned in a functionally equivalent complementarity of shape in an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4. In view of the substantial guidance presented in the specification with regard to the amino acid sequence of SEQ ID NO: 4 and amino acid residues conserved among the functionally related members of the histamine and serotonin binding protein family of the present invention (see, for example, Figure 22), one of skill in the art could practice the presently claimed invention without undue experimentation. That being the case, Applicants assert that the instant claims are enabled by the specification.

The references relied upon by the Examiner in the context of the above-indicated rejection, including Yoon et al. (Structure 13:551-564, 2005); Jeffery et al. (Protein Eng. 13:105-112, 2000); Price et al. (Adv. Drug Deliv. Rev. 56:301-319, 2004); Dahl et al. (Basic Clin. Pharmacol. Toxic. 96:151-155, 2005); and Mans (Curr. Opin. Investig. Drugs

6:1131-1135, 2005) have been considered, but in view of the amendments to the claims, Applicants believe that the issues raised regarding these references have been addressed. The Examiner has referred again to numerous previously cited references supportive of the contention “that function can not be predicted from structure alone”. The list of references includes the following: Bork (2000, Genome Research 10:398-400); Skolnick et al. (2000, Trends in Biotech. 18(1):34-39); Doerks et al. (1998, Trends in Genetics 14:248-250); Smith et al. (1997, Nature Biotechnology 15:1222-1223); Brenner (1999, Trends in Genetics 15:132-133); and Bork et al. (1996, Trends in Genetics 12:425-427). As previously stated, these references largely pertain to genome wide sequence analysis and functional annotation of newly identified nucleic acid sequences. These references emphasize that functional annotation, in the absence of corroborative experimental data, is not reliable. In keeping with previously presented arguments, Applicants assert that the present invention is directed to a member (SEQ ID NO: 4) of a family of structurally and functionally related proteins and to highly homologous amino acid sequences possessing the recited structural/functional properties. The functional properties of this family of proteins have been proven experimentally. As such, the presently claimed amino acid sequences are not sequences determined by genome wide sequence analysis, and for which functional attributes are ascribed based solely on sequence alignment. Applicants, therefore, maintain that these references have little relevance to the presently claimed sequences. In view of the amendments to the claims, and arguments presented herein and previously, Applicants believe that the issues raised regarding these references have been addressed.

With respect to the Examiner’s contentions that undue experimentation would be required to treat or prevent allergic asthma using the methods of the invention, Applicants believe that the instant claims are directed to sequences and methods of using same that are enabled by the specification.

In view of the amendments to the claims and Applicants’ arguments, Applicants believe that the above rejection of claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 under 35 USC § 112, first paragraph, has been obviated and respectfully request reconsideration and withdrawal of this rejection.

Claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 are rejected under 35 USC § 112, first

paragraph, for allegedly failing to comply with the written description requirement. In view of Applicants' arguments presented herein and amendments to the claims, the rejection, as it applied to claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34, is respectfully traversed.

As indicated above, claim 1 is amended to be directed to an isolated histamine or serotonin binding protein capable of binding to histamine or serotonin with a dissociation constant of less than  $10^{-7}$ M, wherein said isolated histamine or serotonin binding protein i) comprises the amino acid sequence of SEQ ID NO: 4 or an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4; and ii) which has a binding site comprising amino acid residues isoleucine at position I, tryptophan at position II, aspartate at position III and glutamate at position IV wherein residues I to IV are positioned at residues 139, 71, 67 and 112 in SEQ ID NO: 4 or are positioned in a functionally equivalent complementarity of shape in an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4. In view of the description of SEQ ID NO: 4 and recitation of residues critical for maintaining the structure/function of SEQ ID NO: 4 and the high degree of homology called for in claim 1, Applicants assert that the written description requirement has been satisfied with respect to the instant claims.

In view of the amendments to the claims and Applicants' arguments, the rejection of claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 under 35 USC § 112, first paragraph, on the basis of an alleged lack of written description, is nullified and Applicants respectfully request reconsideration and withdrawal of this rejection.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection of instant claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 under 35 U.S.C. §112, first paragraph.

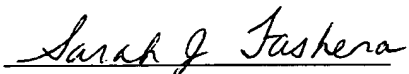
#### *Fees*

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

***Conclusion***

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. Allowance of all claims at an early date is solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

  
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Enclosures:      Petition for a Two-Month Extension of Time